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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,840	08/29/2003	Richard G. Cartledge	52817/292102	8172

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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/651,840

Applicant(s)

CARTLEDGE ET AL.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/26/04, 2/23/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: 1-29/04, 9/15/03.

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Line 10 of the abstract employs "means for" language which should be avoided in the abstract. Please make the appropriate corrections.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Vincent (US 5601604).

Regarding Claim 1, Vincent teaches an implantable device for controlling the internal circumference of an anatomic orifice or lumen, comprising:
an annular ring (10); means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen (13a); means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first

circumference to a second circumference (16); and means associated with said annular ring for maintaining said ring in said first circumference and, upon said annular ring being adjusted to said second circumference, for maintaining said annular ring in said second circumference (Column 3, proximate lines 5-15).

Regarding Claim 6, Vincent teaches the implantable device of Claim 1, wherein said means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen comprises a plurality of grommets (13a, 18a) spaced around the periphery of said annular ring.

Regarding Claim 10, Vincent teaches the implantable device of Claim 6, wherein said grommets comprise tabs (13, 18), and wherein said tabs define holes through (13a, 18a) which a suture can be placed and then through the underlying tissue to anchor said annular ring to the tissue around said anatomic orifice or lumen.

Claims 1 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Bryant et al. (US 6676789).

Regarding Claim 1, Bryant teaches an implantable device for controlling the internal circumference of an anatomic orifice or lumen, comprising:
an annular ring (32); means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen (36); means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference (36); and means associated with said annular ring for maintaining said ring in said first circumference and, upon said annular ring

being adjusted to said second circumference, for maintaining said annular ring in said second circumference (44).

Regarding Claim 11, Bryant teaches the implantable device of Claim 1, wherein said means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference comprises corrugations (40).

Claims 1, 5, 15 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahmadi et al. (US 4602911).

Regarding Claim 1, Ahmadi teaches an implantable device for controlling the internal circumference of an anatomic orifice or lumen, comprising:
an annular ring (101); means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen (107 and Column 1, proximate lines 5-10); means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference (40); and means associated with said annular ring for maintaining said ring in said first circumference and, upon said annular ring being adjusted to said second circumference, for maintaining said annular ring in said second circumference (40).

Regarding Claim 5, Ahmadi teaches the implantable device of Claim 1, wherein said means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen comprises an outer fabric sheath (Column 1, proximate lines

5-10) covering said annular ring through which sutures can be placed to suture said implantable device to said tissue around said anatomic orifice or lumen.

Regarding Claim 15, Ahmadi teaches the implantable device of Claim 1, wherein said means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference comprises: teeth (12) formed on at least a portion of said annular ring; a gear (15) engaging said teeth of said annular ring (Fig. 5); and said gear and said teeth being arranged such that turning said gear effects relative movement between a first end of said annular ring and a second end of said annular ring to adjust the circumference of said annular ring from a first circumference to a second circumference (Column 3, proximate lines 37-46).

Regarding Claim 17, Ahmadi teaches the implantable device of Claim 15, wherein said gear (15) is mounted in fixed relation to said second end (11) of said annular ring, and wherein said teeth (12) are formed adjacent said first end of said annular ring (2).

Regarding Claim 18, Ahmadi teaches the implantable device of Claim 15, further comprising means for turning said gear (48) from a location remote from said gear (51), such that said circumference of said implant can be adjusted after closure of surgical incisions and resumption of physiological flow through said orifice or lumen (Column 6, proximate lines 1-5).

Regarding Claim 19, Ahmadi teaches the implantable device of Claim 18, wherein said means for turning said gear from a remote location is disengageable from said gear after completion of adjustments (Column 5, proximate lines 29-35).

Regarding Claim 20, Ahmadi teaches the implantable device of Claim 1, wherein said means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference comprises:

a worm gear (15); and means operatively associated with a first end of said annular ring for engaging said worm gear (40) such that rotation of said worm gear effects relative movement between said first end of said annular ring and a second end of said annular ring to adjust the circumference of said annular ring from a first circumference to a second circumference (Column 3, proximate lines 37-46).

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Ortiz et al. (US 6419696).

Regarding Claim 1, Ortiz teaches an implantable device for controlling the internal circumference of an anatomic orifice or lumen, comprising:
an annular ring (52); means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen (44a); means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference (Column 2, proximate lines 52-55); and means associated with said annular ring for maintaining said ring in said first

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circumference and, upon said annular ring being adjusted to said second circumference, for maintaining said annular ring in said second circumference (44a).

Regarding Claim 2, Ortiz teaches the implantable device of Claim 1, wherein said means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen comprises a plurality of barbs (44a) extending from said annular ring for engaging the tissue around said anatomic orifice or lumen.

Regarding Claim 3, Ortiz teaches the implantable device of Claim 2, wherein each of said barbs is oriented in a consistent, tangential direction (44a, Fig. 5b) with respect to the annular ring such that rotational motion of the annular ring in a first direction will engage said retention barbs with the desired tissue, and rotational motion of the annular ring in a direction opposite to said first direction will disengage said retention barbs from said desired tissue.

Regarding Claim 4, Ortiz teaches the implantable device of Claim 3, wherein each of said barbs further comprises a hook (164) at its free end.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilbertson et al. (US 5604431).

Gilbertson teaches an implantable device for controlling the internal circumference of an anatomic orifice or lumen, comprising:
an annular ring (10); means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen (42); means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference (12, 18, 20); and means associated with said

annular ring for maintaining said ring in said first circumference and, upon said annular ring being adjusted to said second circumference, for maintaining said annular ring in said second circumference (Column 5, proximate lines 1- 5).

Regarding Claim 11, Gilbertson teaches the implantable device of Claim 1, wherein said means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference comprises corrugations (Column 2, proximate lines 25-35).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmadi et al. in view of Berreklouw (US 6790229).

Ahmadi teaches all aspects of dependent claim 1 as previously described, but fails to disclose wherein said means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen comprises a plurality of barbs extending from said annular ring for engaging the tissue around said anatomic orifice or lumen. Berreklouw teaches a fixing device for fixing to vascular wall tissue

Claims 15, 16 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmadi et al. (US 4602911).

Ahmadi teaches all limitations of dependent claims 1, 15 and 20 as previously described, and further discloses the following limitations:

- means for turning said shaft (51) from a location remote from said worm gear (48)
- implant can be adjusted after closure of surgical incisions and resumption of physiological flow through said orifice or lumen (Column 6, proximate lines 1-5).
- shaft and said means for turning said shaft from a remote location are disengageable from said worm gear after completion of adjustments (Column 5, proximate lines 29-35).

Ahmadi fails to disclose wherein

- The gear system comprises a wheel positioned tangentially to said gear such that said portion of said annular ring which engages said gear passes between said gear and said wheel.
- worm gear has a first angled gear head at its driven end,

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- a shaft in offset relation to said worm gear and having a second angled gear head at a first end thereof,
- first and second angled gear heads drivably engaging such that rotation of said shaft drives said worm gear.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the gear assembly of Ahmadi first by adding a wheel positioned tangentially to said gear such that said portion of said annular ring which engages said gear passes between said gear and said wheel, then adding a first angled gear head at its driven end, a shaft in offset relation to said worm gear and having a second angled gear head at a first end thereof, first and second angled gear heads drivably engaging such that rotation of said shaft drives said worm gear since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions (to drive the worm gear) as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbertson in view of Carpentier et al. (US 6217610). Gilbertson teaches all limitations of claim 1 as previously described, and further discloses the following limitations:

- wherein said annular ring comprises a hollow tube (34, 36) formed into an annular shape (10)

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- tube having interspaced smooth and corrugated sections disposed around its circumference (Column 2, proximate lines 25-35)
- means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen (36) comprises said tube being sufficiently soft such that a suture (42) can be passed through said
- means associated with said annular ring for permitting adjustment of the circumference of said annular ring from a first circumference to a second circumference comprises said corrugated sections (Column 2, proximate lines 25-35)
- tube having portions of narrowed circumference (36) such that a suture (42) can be passed around said tube at said portions of narrowed circumference and hence through the underlying tissue (Fig. 4)

Gilbertson fails to disclose wherein the corrugated sections are sufficiently stiff.

Carpentier teaches an expandable angioplasty ring wherein the tubing comprising the annular ring is made of a sufficiently expandable yet rigid material in order to enhance the device's ability to change size yet maintain a desired circumference. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Gilbertson with corrugated sections sufficiently stiff to maintain annular ring at a desired circumference as taught by Carpentier in order to enhance the ability of the device to adjust the size of the device and maintain the desired circumference afterward.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbertson in view of Blomme (US 6911035).

Gilbertson teaches all limitations of dependent claim 1 as previously described, but fails to disclose wherein means by which the ring is fastened to the tissue comprises a plurality of grommets having a narrowed intermediate neck portion. Blomme teaches a vascular suturing device comprising a plurality of grommets (13) with narrowed neck portions (11) in order to increase the devices ability to connect to the underlying tissue. It would have been obvious to one of ordinary skill in the art to modify the device of Gilbertson with a plurality of grommets with narrowed neck portions as taught by Blomme in order to increase the devices ability to connect to the underlying tissue.

Claims 6, 8, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbertson as a matter of design choice. Gilbertson teaches all limitations of preceding dependent claim 1, but fails to disclose wherein the fastening means comprises a plurality of grommets in the form of tabs that are sufficiently soft that a suture can be placed through. It would have been obvious matter of design choice to modify the Gilbertson reference by having the fastening means comprises a plurality of grommets in the form of tabs that are sufficiently soft that a suture can be placed through, since the applicant has not disclosed that having the fastening means comprising a plurality of grommets in the form of tabs that are sufficiently soft that a suture can be placed through solves any stated problem or is for any particular purpose and it appears that the circumference controlling device of Gilbertson would perform

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equally well with sutures being placed directly through the ring (Fig. 4) or with sutures placed through grommets.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
12/12/05


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
